

3. Summary

APR - 4 2002

K020933
page 1 of 3**Common Device Name:** Portable Wheelchair Lift**Trade Name:** Super-Trac TRE-52**Predicate Device:** Stair-Trac
K981518

Device Description: The Super-Trac TRE-52 is a portable wheelchair lift designed to carry a passenger in a wheelchair up and down stairs. It is a mobile, attendant-operated device that will accommodate most child and adult wheelchairs, including power wheelchairs and sports wheelchairs.

The Super-Trac TRE-52 consists of two endless durable belt tracks driven by two 12 volt DC motors. Two 12 volt 24 AH rechargeable batteries are used to power the motors. The device includes a set of auxiliary wheels that assist in maneuverability on landings.

The wheelchair fits onto a platform that is mounted to the drive frame. Loading is by means of an integrated ramp that slides out from below the platform. The wheelchair is secured to the platform using four tie-down straps and a seatbelt that goes around both the passenger and wheelchair. The platform is tilted to the stair-travel position by a hydraulic actuator located on the drive frame.

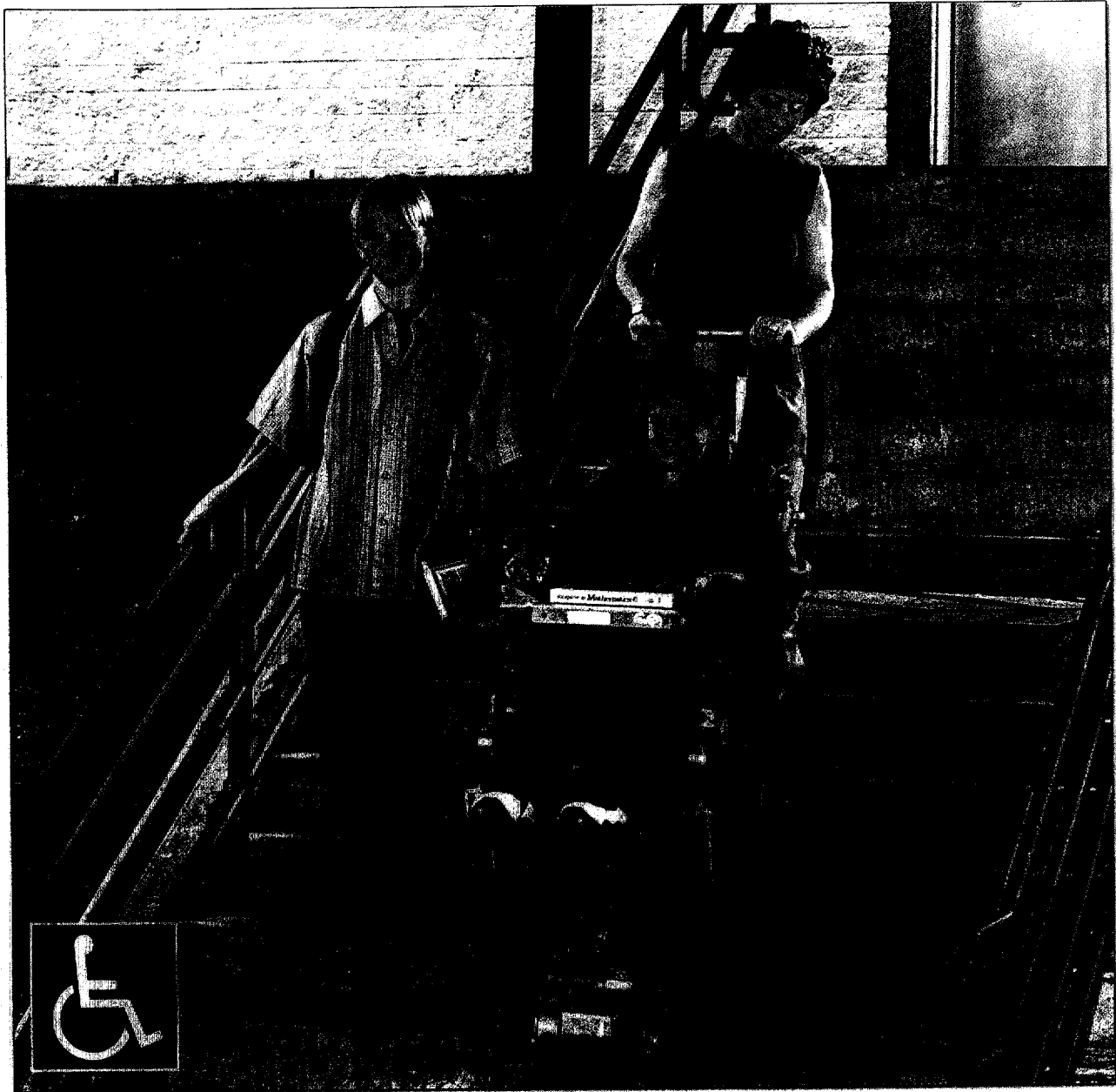
Super-Trac is equipped with a key switch to restrict use to authorized persons. A stair-slope indicator is provided to determine the stair angle is within the operating range.

The attendant operates Super-Trac TRE-52 from controls located on the operating handle. Super-Trac TRE-52 is designed for use on both indoor and outdoor stairways.

See attached brochure.

Garaventa Stair-Trac

portable wheelchair lift



The Garaventa Stair-Trac is an easy to use, portable wheelchair lift designed to attach under most manual wheelchairs. Stair-Trac's powerful motor allows a small attendant to safely transport a larger passenger up and down stairways. Stair-Trac is suitable for indoor or outdoor use in public buildings and private homes. An affordable and reliable portable access solution.

Specifications

Load Capacity 130kg/285lbs
 Power Capacity 650 stairs
 Maximum Speed
 Up Stairs 8.0m (26.3ft)/min
 Down Stairs 12.5m (41.0ft)/min
 Motor 12 VDC
 Batteries 2 x 6V - 20AH
 Max. Charge Rate 4 amp
 Optimum Stair Angle 35°

Dimensions

Height 935mm/36.8in
 Depth 1473mm/58.0in
 Width 635mm/25.0in

Weight

Drive Frame 39kg/86lbs
 Support Handle 15kg/33lbs
 Total Weight 54kg/119lbs

Clearances

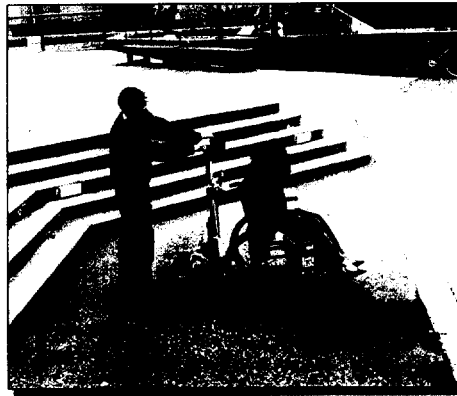
Wheelchair loading/unloading requires a minimum straight line clearance of approximately 3m/10ft. The diagram below shows typical clearances required on turnback stairways. Dimensions vary with stairway width and operator experience. Consult Garaventa or your local representative for clearance verification.

2250mm 88.6in		1300mm 51.18in	
915mm 36.0in		915mm 36.0in	

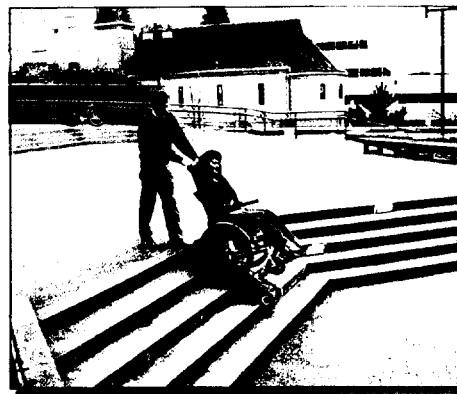
Garaventa Accessibility

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 Toll Free: 1-800-663-6556
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 Web Site: www.garaventa.ca

Stair-Trac



Attach the Stair-Trac to the wheelchair, recline the passenger and move them to the stairway.



Ascend or descend stairs with the press of a button. The passenger sits in a comfortable, upright position.



The Stair-Trac is easy to load into vehicles using the optional loading ramp, and fits easily into most car trunks.

Features

- Attaches to most standard wheelchairs with push handles (adult/child)
- Powered to carry over 250 lbs. up approximately 30 floors
- Use on virtually any indoor or outdoor stairway
- Stable and self-supporting
- Durable tracks grip stairs securely
- Detachable support handle for compact storage and easy transport
- Quick-release safety belt
- Key switch restricts use to authorized persons
- Optional auxiliary seat for non-wheelchair passengers
- Rechargeable batteries and charger

Benefits

- Economical compared to stairway lifts and elevators
- Can be used on various stairways within a building
- Can be used when electrical power fails or is not available
- Easily stores in a secure area when not in use
- Requires minimal maintenance
- Available immediately

What our customers say

"The Garaventa Stair-Trac has allowed our District to meet its needs at a fraction of the cost of installing an elevator in our building."

- Batavia City Schools, Batavia, NY

"It has proven to be dependable, safe, and functional for our school district."

- Hillcrest Elementary, American Falls, ID

Coming soon...The Super-Trac

The portable wheelchair lift for custom and power wheelchairs.
 Available April, 2002



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 4 2002

Mr. Norm Cooper
Director of Sales & Marketing
Garaventa Accessibility
P.O. Box 1769
Blaine, Washington 98231-1769

Re: K020933

Trade/Device Name: Garaventa Super-Trac TRE-52 Portable Wheelchair Lift
Regulation Number: 890.3930
Regulation Name: Wheelchair Elevator
Regulatory Class: Class II
Product Code: ING
Dated: March 20, 2002
Received: March 22, 2002

Dear Mr. Cooper:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

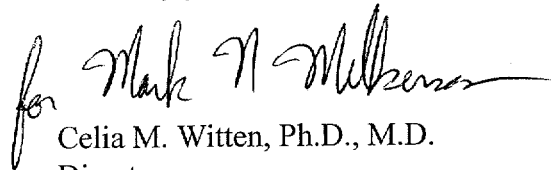
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Norm Cooper

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "for Mark N. Milken", is written over the typed name of the signatory.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Statement of Indications For Use

510(k) Number: K020933

page 1 of 1

Device Name: Super-Trac TRE-52
Portable Wheelchair Lift

Indications for Use:

The Super-Trac TRE-52 is intended to mechanically transport a single individual in a wheelchair up and down stairs in a private or public facility. The Super-Trac must be operated by a trained attendant.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Milken
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices
510(k) Number K020933

Prescription Use X
(Per 21 C.F.R. Section 801.109)

OR

Over-the-Counter Use _____